

***Cancer Detection Programs:
Every Woman Counts***

**PROGRAM
MANUAL FOR
PRIMARY CARE
PROVIDERS**



Cancer Detection Programs:
Every Woman Counts

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1 SECTION ONE: INTRODUCTION TO THE CLINICIAN MANUAL

Welcome to *Cancer Detection Programs: Every Woman Counts (CDP:EWC)*. This Program is designed to provide breast and cervical cancer public education and outreach, screening, follow-up diagnostic services, case management, and rescreening for low income uninsured or underinsured women in California. The Cancer Detection Section (CDS) manages the multi-faceted Program and is a part of the California Department of Health Services' Chronic Disease and Injury Control Division.

CDP:EWC strives to combat breast and cervical cancer both the at state and local level, by providing clinical services, quality assurance, professional education, research and surveillance, public education and outreach, and marketing campaigns throughout the year.

Program services are provided **at no cost to eligible women**. The Program's priority populations are women 50 years and older and African American, Asian/Pacific Islander, American Indian, Rural women, and rarely or never screened women.

This manual is designed to help providers follow CDS Clinical Standards when enrolling, examining, following and re-screening program eligible women. The manual is divided into sections, which address the scope of the Program, patient eligibility and enrollment, provider qualifications and expectations, clinical standards, referrals, quality assurance, billing, data collection, and available resources for information and support.

Program providers have a critical role by providing access to care for underserved women with the intent of detecting cancer at an early stage and decreasing mortality.

1.1 CDS Mission and Vision

The mission of CDS is to save lives by preventing and reducing the devastating effects of cancer for all Californians through early detection, diagnosis and treatment, with special emphasis on the underserved.

The vision of CDS is to:

- Reduce the disparities in the cancer burden.
- Ensure that all Californians have access to high quality cancer education, early detection, diagnosis and treatment
- Have a valued and expert workforce.
- Be a leader in cancer detection and control.

- Influence healthcare systems to provide quality services.

Program goals for breast and cervical screening are:

- To reduce mortality through breast and cervical cancer screening.
- To stimulate changes in health care and mobilize communities to enable all women to receive timely, high quality breast and cervical cancer services.

1.2 Cancer Detection Section Facts

Both state and federal dollars fund the Program. Breast and cervical cancer screening services receive funding from the Centers for Disease Control and Prevention under the Breast and Cervical Cancer Mortality Prevention Acts of 1990 (Public Law 101-354). Funding for breast cancer screening and diagnostic services is also received from 50% of revenues collected from a 2-cent tax on tobacco products, mandated by the California Breast Cancer Act of 1993.

A statewide consortium of providers offers breast cancer screening, diagnostic and treatment services. A limited number of providers are authorized to provide cervical as well as breast cancer screening services.

1.3 Program Covered Services

Following is a brief description of Program services. Refer to the Cancer Detection Programs: Every Woman Counts section of the Medi-Cal Manual for Program reimbursable procedures. The manual is located on the Medi-Cal website at <http://www.medi-cal.ca.gov>.

BREAST CANCER SCREENING AND DIAGNOSTIC SERVICES FOR WOMEN AGE 40 AND OLDER

Office Visit – Breast Screening

A clinical breast examination (CBE) is reimbursable. Repeat exams are allowed for follow-up. Follow-up breast examinations, if indicated, are also reimbursable.

Screening Mammography

A screening mammogram is reimbursable.

Abnormal CBE/Mammogram Results

When a CBE or screening mammogram is abnormal, a diagnostic work-up should be initiated which may include a diagnostic mammogram and/or other diagnostic procedures.

Diagnostic Mammography

A diagnostic mammogram is reimbursable when either the CBE or the mammogram is abnormal. Repeat diagnostic mammograms, if indicated, are also reimbursable.

Other Diagnostic Services

Additional reimbursed breast diagnostic services include ultrasound, Fine Needle Aspiration (FNA), core needle and/or excisional biopsies. Diagnostic services are reimbursed until a pathologic diagnosis of cancer or not cancer is made. Cancer treatment is not covered by *CDP:EWC*. The woman can be referred to the Breast and Cervical Cancer Treatment Program (BCCTP), for assistance with cancer treatment costs (see Section 7-1).

CERVICAL CANCER SCREENING AND DIAGNOSTIC SERVICES FOR WOMEN AGE 25 AND OLDER (For providers authorized to provide cervical services for the Program)

Office visit – Cervical Screening

A cervical screening visit (pelvic-exam and Pap smear) is reimbursable for women:

- Who have not had a hysterectomy,
- Who have had a supracervical hysterectomy,
- Who have had a total hysterectomy due to cervical cancer.
- Who have had a hysterectomy status unknown.
- Who have had a hysterectomy cause unknown.

A cervical screening visit is not reimbursable for women who have had a total hysterectomy for reasons other than cervical cancer.

A cervical screening visit is reimbursable:

- Annually until the woman has had three consecutive normal Pap smears.
- After documentation of three consecutive annual normal Pap smears one every three years or at the provider's discretion. After three annual consecutive normal Pap smears, the woman is to be screened once every three years or at the provider's discretion. For more information, see Section 4 regarding CDS Clinical Standards.
- For women who have no cervix due to cervical cancer.
- Repeat Pap smear is indicated.

Colposcopy

- A colposcopy and up to four biopsies (Endocervical Curettage (ECC) - billed as a biopsy) is reimbursable when either the Pap smear or the visual inspection of the cervix is abnormal.
- Diagnostic services are reimbursed until a final pathology diagnosis is made. Treatments for diagnoses of CIN II, CIN III, HSIL and cervical cancer are not covered by *Cancer Detection Programs: Every Woman Counts*. The woman may be referred to BCCTP for assistance with precancer/cancer treatment costs (see Section 7-1).

2 SECTION TWO: PROVIDER PARTICIPATION

To participate in the *Cancer Detection Programs: Every Woman Counts (CDP:EWC)*, primary care providers (PCP) must be invited to participate by a Regional Office Clinical Coordinator, must be a Medi-Cal provider in good standing, and follow all Medi-Cal rules and regulations, including reporting change of address to Medi-Cal. PCPs must sign a provider enrollment agreement indicating an understanding of their obligations as CDP:EWC providers. All PCPs are authorized to perform and obtain reimbursement for program covered breast services. A limited number of providers will be authorized to offer Program reimbursed cervical services. Provider eligibility requirements for the Program are subject to change at the discretion of CDS.

All providers must agree to accept Medi-Cal reimbursement rates as payment in full, and not to bill eligible patients for Program covered services. All Program services must be in compliance with all applicable federal, state, and local laws, and regulations, and delivered within accepted professional standards of care.

All providers of the Program must have undergone appropriate training for their clinical scope of practice, and regularly update their clinical skills. The Department of Health Services (DHS) has developed continuing education courses that are available to providers. Providers are encouraged to take advantage of these training opportunities. Training information can be obtained from the Regional Office Clinical Coordinator .

Providers must use a laboratory which is licensed by DHS Laboratory Field Services or is Clinical Laboratory Improvement Act (CLIA) certified. Cervical cytology interpretation must be reported using the latest Bethesda System endorsed by the American Society for Colposcopy and Cervical Pathology (ASCCP).

The provider must use a radiology facility that has a current California license and a federal Food and Drug Administration certificate. Mammography interpretation must be reported according to Mammography Quality Standard Act (MQSA) requirements.

Within the Program there is a distinction between the roles and responsibilities of the PCP and that of the referral provider. PCPs are enrolled in *CDP:EWC* through a Regional Office Clinical Coordinator. Enrollment is based on the need for complete service networks in a geographic area and/or for improved access to care for priority populations. Referral providers receive referrals from Program PCPs to render specialized screening or diagnostic services. They must be a Medi-Cal provider in good standing. Referral providers do not enroll in *CDP:EWC* or sign a provider enrollment agreement.

2.1 Primary Care Provider Qualifications

The PCP must meet the following qualifications:

- Be an established provider of outpatient clinical services in good standing with Medi-Cal.
- Have web-based access to Medi-Cal with a valid Medi-Cal provider number and PIN (ID number) in order to access the patient enrollment and data submission application on the Internet.
- Prior to providing services, receive orientation from the Regional Office Clinical Coordinator and the Electronic Data Systems' (EDS) field representative to understand Program requirements, electronic data submission and electronic/hard copy claim submission. The EDS Rep can be accessed via the Telephone Service Center (TSC) 800-541-5555 number.

2.2 Primary Care Provider Roles and Responsibilities

The PCP must ensure that:

- Documentation related to women's self-proclaimed program eligibility is available upon request.
- Women sign a consent that indicates participation in the program and receipt of Notice of Privacy Practices (NPP).
- Women are given their Recipient ID Card that allows services to be billed to *CDP:EWC*.
- Women receive only program covered services unless there is full disclosure to the woman that she is receiving services for which she will be billed.
- Women receive appropriate breast and cervical cancer screening.
- All data are entered on each woman served per CDS policy.
- Minimum Data Elements (MDEs) are submitted electronically per program requirements. See Section 2.3 for a description of MDEs.
- Women will be tracked and followed-up until a final diagnosis is obtained.

- Women receive reminders to return for rescreening.

Tracking and Follow-up

The Center for Disease Control and Prevention (CDC), explains, "Tracking entails the use of a data system to monitor a woman's receipt of screening/rescreening, diagnostic, and treatment procedures. Follow-up refers to the provision of appropriate and timely clinical services following an abnormal test result and/or diagnosis of cancer."

Tracking and follow-up are important components of early detection services for breast and cervical cancer. Tracking, follow-up and rescreening have resulted in decreased mortality. Appropriate tracking and follow-up activities ensure that women return for annual rescreenings and receive diagnostic evaluation in a timely manner. The provider must ensure that:

- Women are offered appropriate screening tests in accordance with CDS Clinical Standards.
- All MDEs are submitted electronically according to the following requirements:
 - all abnormal results are submitted within ten (10) days, but no later than thirty (30) days of confirmation of an abnormal finding.
 - all other screening and diagnostic data is submitted within thirty (30) days.
- Women are notified of screening results in accordance to clinical standards (see Section 4.1).
- Women with abnormal screening results receive appropriate education and information to make informed decisions about diagnosis and treatment options.
- Referrals for required diagnostic evaluation or treatment are made in accordance to clinical standards (see Section 4.1).
- Women are tracked for appropriate cervical screening services.
- Women are reminded of the need for annual rescreening consisting of a clinical breast examination, and a mammogram and a Pap smear, if indicated.
- Three attempts must be made to notify women of the need for annual rescreening and the need for follow-up diagnostic and treatment services

for abnormal screening results before they are considered lost to follow-up. The third attempt must be by certified letter.

Case Management

CDP:EWC focuses on key components to reduce mortality from breast and cervical cancer. These components are: annual routine screening, timely diagnosis of abnormal screening results, and timely initiation of treatment if cancer is diagnosed. Lives can be saved only if women who need services are systematically identified, referred, and given access to recommended health care services.

Case management is a vital office system to ensure that women receive timely services. Case management establishes and sustains systems of clinic and support services for women and identifies and refers women needing services. Assigning specific tasks to specific staff enhances the success of this vital office system. *CDP:EWC* defines seven key elements of case management:

Identification – Systematically determine through the use of tracking and follow-up systems, all those women with rescreening, diagnostic, and treatment needs.

- Regularly identify women who need to return for annual rescreening.
- Identify women who have abnormal breast or cervical cancer screening findings and need diagnostic studies.
- Identify women who have been diagnosed with breast or cervical cancer.

Assessment – Determine the factors that may keep each woman from receiving recommended services.

- Assess each woman's practical, cultural, and educational barriers to care, such as, transportation, childcare, language, fears, myths, lack of knowledge or misunderstanding about procedures.

Planning – Determine the individual woman's barriers, identify solution and document the plan.

- Discuss possible solutions to barriers identified in the assessment with the woman.
- Explain the resources available and how to access them.

Coordination – Assist the woman to receive the recommended healthcare.

- Check whether follow-up or annual screening appointments were made and services received.

Monitoring – Re-assess the woman’s needs and the ability to adhere to recommended services as the diagnostic work-up continues.

- Assess for new information and support service needs as the diagnostic cycle evolves.

Resource development – Locate or negotiate for community resources that will improve access or utilization of healthcare services.

- When necessary, establish agreements to obtain screening, diagnostic, treatment, or support services.
- Ensure clinic staff is aware of community resources.
- Organize often-used support services information into an easily accessible form for clinic staff use.

Evaluation – Assess woman satisfaction and access to services received.

- Compare own practice outcome trends.

Quality Assurance

CDS has a multifaceted quality improvement program that serves to continually enhance the early detection of cancer throughout California. Through data collection and evaluation, CDS identifies areas needing assistance as well as areas of best practices in the Program. The elements of the quality improvement the PCP participates in are: periodic site reviews, chart abstractions, and timely data collection/submission.

Provider Site Reviews

Provider site reviews are conducted periodically to assess the provider’s success in creating and maintaining systems to enhance screening, follow-up and rescreening of women enrolled in the Program. Emphasis is placed on reviewing a provider’s performance in meeting MDE data submission requirements. Provider site reviews performed by the Regional Office Clinical Coordinator are scheduled in advance. The provider is expected to assemble documents related to the Program and the Clinical Standards, as well as to have the medical records for enrolled women available.

At the time of the provider site review, technical assistance is provided by the Regional Office Clinical Coordinator. This is followed by a post-review letter describing any areas needing improvement. Follow-up may be conducted to review success in instituting the recommended improvements. If the Clinical Coordinator determines a provider has consistently not met the Program Clinical Standards, the provider may be given a limited time to comply with the standards before the disenrollment process is initiated.

Aggregate data obtained during provider site reviews may be used for Continuous Quality Improvement (CQI) Projects. Feedback from the site reviews

is used to further enhance the systems in place at various provider sites in the region.

Blocking Referrals from the 800 Number

A PCP wishing to block referrals to his practice, must put this in writing to the 800 Number. The letter must be on letterhead and signed. A copy is to be sent to the Regional Office Clinical Coordinator.

Chart Abstractions

Periodically, Program or contract staff may require access to medical office records of Program women for quality assurance purposes. CDS reserves the right to abstract data for Program implementation, research needs, or to correct missing data elements required for Program funding documentation.

2.3 Primary Care Provider Responsibilities for Data Collection Requirements and Reporting

MDEs

MDEs are a set of standardized data elements developed to ensure that consistent and complete information on screening location, patient demographic characteristics, screening results, diagnostic procedures, tracking and follow-up, and treatment information are collected on women screened and/or diagnosed with National Breast and Cervical Cancer Early Detection Program (NBCCEDP) funds. These are the data items that are minimally necessary for NBCCEDP-sponsored Programs and CDC to monitor clinical outcomes. MDEs are incorporated into CDS' clinical standards and woven into all tenets of *CDP:EWC*. MDEs are collected for each woman served in the program and are converted into a standardized format. These MDEs are collected via *CDP:EWC* web-based breast/cervical screening and follow-up forms. Providers must notify CDS of all abnormal results within ten (10) days but no later than thirty (30) days of confirmation of an abnormal finding. They must also submit all other findings within thirty days. This is accomplished by submitting data on the web-based screening and follow-up forms.

As explained, web-based data submission for PCPs is required for *CDP:EWC*. The provider will report data as mandated by CDS, using online breast/cervical screening and follow-up forms. These forms collect data on screening, timely follow-up for abnormal screening results, diagnostic procedures, outcomes, final diagnosis, treatment disposition (if warranted), and rescreening information. This data is used for program quality improvement, is submitted to Program funders, and is used to determine CDS' ability to continue funding services. CDS evaluates the data for completeness and correlation with Program Standards

(see Section 4). Feedback and/or technical assistance through the Regional Office Clinical Coordinator will be provided as needed. Guidelines for completing the data forms are available in the *CDP:EWC Step-By-Step Provider User Guide*. This guide is available at: (<http://www.medi-cal.ca.gov>). Assistance with the technical performance of the web-based forms can be obtained by calling the POS/Internet Help Desk/TSC at (800) 541-5555.

CDS Data Reports

CDS staff will also send data reports to individual providers on their status with submitted data completion. These reports are sent confidentially to an assigned provider staff member who has been identified to receive personal health information on women with missing data or unclear outcomes. These reports should be taken seriously as data are an intricate and vital part of Program funding and the ability to continue to participate in the program. Timely data submission is an important factor for CDS regarding provider evaluation.

Provider Responsibilities for Data Collection

All CDS PCPs are required to be enrolled in the Program and have on file a current/signed Provider Enrollment Agreement (PEA). This agreement means that the PCP will follow CDS Program Clinical Standards and provide accurate data for each woman served with Program funds in a timely fashion. CDS retains the right to require providers to take part in remedial training to maintain their status as a Program PCP when providers fail to adhere to Program requirements.

Warnings for Data Deficiencies

CDS strives to assure that all women receive appropriate and timely screening services and follow-up. To assist in this process, CDS continually monitors enrolled women to assess data submitted per program requirements. Providers who are not meeting program requirements will be informed in writing. Providers are to comply with all Medi-Cal requirements regarding reporting of address changes so that CDS has access to the correct address via Medi-Cal files.

Additional CDS Data Reports

CDS furnishes reports to providers that are at risk of being out of compliance with data requirements. Reports are also provided to the Regional Office Clinical Coordinator. The Regional Office Clinical Coordinators are available to provide technical assistance to providers via formal CDS Site Reviews, office assessment of systems, and additional support from sources such as EDS, and classes. Web-based resources may also be made available.

Provider Warning of Disenrollment

A provider that does not meet CDS data requirements will be given a written warning. The provider must submit all complete and accurate data within 60-days or must submit a correction plan that includes a summary of the problem and the actions to be taken to solve the problem. Providers that have received a warning and are choosing the option of the correction plan are requested to submit their plan to CDS at the earliest possible date within the 60-day time frame, in order for interventions to begin as soon as possible. If appropriate, a provider that has submitted a correction plan may be provided technical assistance and/or training from CDS. Providers who have submitted a corrective action plan must begin to submit required data within 30 days of submitting the correction plan to CDS.

Provider Disenrollment

Failure to respond to CDS with either the submission of data or a correction plan at the end of 60-days shall result in automatic disenrollment from the program. Providers that receive a warning and technical assistance/training, and then continue to fail to submit data, will be automatically disenrolled. Disenrolled providers that may want to reenter the program at a later date must satisfactorily demonstrate ability to meet all program requirements.

Appeal Process

Any provider that chooses to appeal disenrollment must file a written appeal that includes:

1. The issue(s) in the dispute
2. The legal authority or other basis for the appellant's position
3. The remedy sought.

Appeals that do not include all of these areas shall be rejected. Appeals may be mailed or faxed to:

Donald O. Lyman, M.D., Chief
Division of Chronic Disease and Injury Control
California Department of Health Services
MS 7200
P.O. Box 997413
Sacramento, CA 95899-7413
Fax (916) 449-5707

Health Insurance Portability and Accountability Act Responsibilities (HIPAA)

As a health plan, CDS is required to protect patient information and inform patients of their rights under HIPAA. To do this, each woman who enrolls in the Program will be given a copy of a Notice of Privacy Practices (NPP) describing

how their medical information may be used or disclosed and how they may access their protected health information. PCPs enrolled in *CDP:EWC* must provide a CDS NPP to enrolled women and maintain the signed original document in each woman's chart. Specific information regarding these responsibilities is explained during your program orientation. Additional information can be obtained at: <http://www.medi-cal.ca.gov>

Leaving the Program

If the PCP decides he/she no longer wishes to continue with the Program, the provider may choose to voluntarily disenroll. The provider must send a letter to the Regional Office Clinical Coordinator requesting disenrollment.

CDS may disenroll a provider from the Program if the provider is no longer in good standing with Medi-Cal, no longer has an active Medi-Cal number, or fails to maintain Program case management, Program Clinical Standards and data collection requirements. The provider will be notified by letter from CDS if these circumstances occur. CDS mandates a waiting period of no less than 6 months for a CDS-initiated disenrollment to be reversed. Problems leading to disenrollment must be resolved before re-enrollment can be considered.

A disenrolling provider is expected to assure that women enrolled in the Program receive continued care. Disenrolled providers are required to refer enrolled women to another Program PCP. For assistance, call the State Consumer 800 number (800) 511-2300 and identify yourself as a provider needing a referral for a patient.

Even after leaving the Program, PCPs are still required to submit data for screening and follow-up services provided during the period of time the provider was enrolled.

2.4 Referral Provider Role and Responsibilities

Referral providers include radiologists, surgeons, pathologists, anesthesiologists, mammography facilities, and hospitals. Referral providers must:

- Be a Medi-Cal provider in good standing.
- Accept women referred by the PCP.
- Provide services according to the Program clinical standards.
- Report all screening and diagnostic findings to the PCP in a timely manner.

- Bill Medi Cal, using the recipient ID number given them by the PCP.
- Accept Medi-Cal reimbursement as payment in full.

3 SECTION THREE: PATIENT ELIGIBILITY

Women must meet the following financial, residency and age criteria to be eligible for enrollment in the Program:

3.1 *Financial Criteria*

Self-reported financial eligibility must be met in order to receive services:

- The woman's household income is at or below 200 percent of the Federal poverty level. These guidelines are adjusted annually April 1st and are published at <http://www.medi-cal.ca.gov>. Guidelines can also be found at <http://aspe.hhs.gov/poverty/index.shtml>
- Household income includes incomes of all family members (the applicant, spouse, and children (age 20 or younger)) living together. When Adults other than spouses reside together, each person shall be considered a separate family.
- The woman must either not have any other public or private source of medical insurance coverage for screening and follow-up services, or not be able to afford unmet deductibles, co-pays, or share of cost for screening and follow-up services.

The *Cancer Detection Programs: Every Woman Counts (CDP:EWC)* is the payer of last resort. All other possible third party payers including private insurance, Medicare, Medi-Cal and Family Planning, Access, Care and Treatment (Family PACT), must be exhausted prior to billing the Program.

Patients who are covered under Medi-Cal at the time of enrollment are ineligible for Program services. Exceptions are made if the woman is receiving emergency Medi-Cal, prenatal Medi-Cal, or has a share of cost which they are unable to meet.

Medicare Part B reimburses for a mammogram every year for women 65 years of age and older. *CDP:EWC* funds may pay for services to women not enrolled in Medicare Part B coverage. In addition, Medicare reimburses for a Pap smear every three years or at provider discretion. Program funds do not reimburse for alternate year cervical cancer screening coverage if the woman is eligible for Medicare Part B.

The Family PACT Program and *CDP:EWC* have the same financial requirements for participation. Women who do not qualify for the Family PACT Program (i.e. no reproductive capability) may be eligible for *CDP:EWC* services if they meet

Program financial, residential and age eligibility requirements. Family PACT women who meet *CDP:EWC* eligibility requirements may utilize the Program for breast and cervical services not covered under Family PACT. However, *CDP:EWC* is the payer of last resort, therefore, all Family PACT covered services must first be exhausted prior to utilizing Cancer Detection Section (CDS) Program services funding.

Women with abnormal screening mammograms paid for through Family PACT or other providers may be referred to CDS providers for continued care. If the patient meets the Program eligibility requirements, the patient may be enrolled in the Program. Enrollment into *CDP:EWC* to receive services mandates the reporting of complete cycle data, even if the services were received outside *CDP:EWC*. Appropriate screening and/or follow-up services will be reimbursed. The prior examination and tests performed can be accepted, or a repeat exam/test can be performed; the data requirements remain. Women may not be enrolled in *CDP:EWC* solely for the purpose of receiving case management services. The patient must be in need of a clinical service not covered by another program.

For any woman that crosses over from Family PACT into *CDP:EWC* for breast or cervical services, the provider must submit both Family-PACT screening outcomes *and* *CDP:EWC* data on the Web-based online breast/cervical screening and follow-up forms.

3.2 Residency Criteria

- Women must have a California address to be eligible for the Program.

3.3 Age Criteria

Women who meet the financial guidelines are eligible for the following reimbursed services:

- Women 40 and older are eligible for breast and cervical cancer screening and diagnostic procedures.
- Women 25 and older are eligible for cervical cancer screening and follow-up.

3.4 Consent

All women participating in the Program must sign the form titled *Consent to Take Part in Programs and Give Personal Medical Facts*. This form may be downloaded from the Medi-Cal website (<http://www.medi-cal.ca.gov>) and is available in English, Spanish Chinese, Russian, Korean, and Vietnamese. The

consent must be signed once every 12 months and be kept in the individual medical record.

3.5 Recipient Eligibility Form

The Recipient Eligibility Form is used to document the woman's income and eligibility data. The form is signed by both the patient and provider and is kept in the medical record. The information contained in the form is used to enroll the woman into the Program. Patient eligibility must be re-certified every year. The form is available at <http://www.medi-cal.ca.gov>

3.6 Online Recipient Information Form

Using the information obtained in the Recipient Eligibility Form, the provider enrolls the patient on the Medi-Cal website. When the enrollment process is completed, the provider will receive a 14-character computer generated recipient ID number. This number is required on all claims from primary care and referral providers. The referral provider obtains the number from the PCP or the patient.

Detailed Program eligibility information is available in the *CDP:EWC* section of the Medi-Cal Manual.

Detailed enrollment procedures are available in the *CDP:EWC* Step-By-Step Provider User Guide available at <http://www.medi-cal.ca.gov>

4 SECTION FOUR: PROGRAM STANDARDS

4.1 Cancer Detection Section (CDS) Clinical Standards

While certain clinical standards are procedure specific, the following standards apply to the entire Program.

Each provider shall implement a tracking and follow-up system, which ensures that:

- All phone/mail contacts with a woman are recorded. When a test result is abnormal, three attempts to contact the woman must be documented, the third attempt must be by certified mail. (Fewer attempts are acceptable if the woman returns for appropriate follow-up care.)
 - If a woman is contacted and refuses care, the reason must be clearly stated in the woman's chart.
- Screening services are provided to eligible women within 30 days of initial request.
- Women are notified of negative test results within 30 days of service.
- Women are notified of abnormal test results within 10 working days of the receipt of test result.
- Referrals for required diagnostic evaluation and/or treatment occur within 10 days of the receipt of test results.
- The maximum elapsed time between initial service and diagnosis is 60 days.
- The maximum elapsed time between a diagnosis of cancer and referral for treatment is 10 working days.
- Women are notified of a diagnosis of cancer within three to five working days of the receipt of test result.
- The maximum elapsed time between a diagnosis of cancer and initiation of treatment is 60 days.
- The provider must assist women with a diagnosis of cancer to secure treatment.
- Women return for annual re-screening.
- A provider must document three unsuccessful attempts to contact a woman before designating her lost to follow-up. The third attempt must be by certified mail.

4.2 Standards Specific to Breast Cancer Screening

- A breast cancer screening cycle begins with a Clinical Breast Exam (CBE) and minimally includes a CBE and followed by a mammography.
- Primary Care Providers (PCPs) must correlate CBE and mammography findings.
- Abnormal CBEs require follow-up despite negative mammography findings. Further diagnostic testing to determine the etiology of an abnormality is required.
- Mammography facilities are required to post a current FDA certificate, indicating compliance with MQSA standards. These standards require reporting of mammography results to the ordering PCP.
- Mammography reports utilize the MQSA reporting system, required by the FDA.
- Radiologists interpreting mammograms must correlate their findings with the CBE described on the order for mammography.
- A “probably benign” (BIRADS 3) finding shall be followed by further evaluation, radiographic or otherwise.
- “Suspicious” (BIRADS 4) and “highly suggestive of malignancy” (BIRADS 5) findings will be communicated to the referring PCP within 3 to 5 days.
- The referring PCP shall assure arrangement of diagnostic follow-up for women needing further evaluation within 10 days of abnormal test results.

Mammography Quality Standards Act

The MQSA requires that mammography reports include the following:

- The name and address of the patient and an additional patient identifier
- The date of examination
- The name of the radiologist` who interpreted the mammogram

- Overall final assessment of findings, classified in one of the following categories:
 - BIRADS Category 1: “Negative”
 - BIRADS Category 2: “Benign findings”
 - BIRADS Category 3: “Probably benign findings-initial short-interval follow-up suggested”
 - BIRADS Category 4: “Suspicious abnormality–biopsy should be considered”
 - BIRADS Category 5: “Highly suggestive of malignancy–appropriate action should be taken”
 - BIRADS Category 6: “Known biopsy/proven malignancy–appropriate action should be taken”
 - BIRADS Category 0: Needs additional imaging evaluation and/or mammograms for comparison”
- Recommendations made to the PCP about additional actions, if any, to be taken. All clinical questions raised by the referring PCP shall be addressed in the report to the extent possible, even if the assessment is negative or benign.

4.3 Standards Specific To Cervical Cancer Screening

CDS adheres to the Centers for Disease Control and Prevention (CDC) guidelines regarding Pap smear results. The CDS Expert Cervical Workgroup defined “Normal” Pap smears (for cervical cancer screening purposes) as those listed under “benign” on the Bethesda (1994) diagnosis list.

Women with three documented, consecutive, normal, Pap smears, performed annually (i.e. within 10-18 months of the last Pap smear) do not receive a fourth annual Pap test (see exceptions below). Thereafter, Pap tests can be can subsequently have repeated every three years.

The CDS Expert Cervical Workgroup has determined that a woman may have an additional consecutive annual Pap smear if any of the following conditions exists:

- History of Squamous Intraepithelial Lesion (SIL), or previous epithelial abnormality.
- History of cervical dysplasia or cervical cancer, or treatment for cervical dysplasia or cervical cancer.

- History of multiple sexual partners, or relations with partners who have a history of multiple sexual partners.
- Smokes, or has a history of smoking within the past year.
- Immunosuppression.
- Sexually transmitted disease or history of sexually transmitted disease.
- Early age at first intercourse.

Reporting Pap-Smear Results

- The most current Bethesda system endorsed by the American Society for Colposcopy and Cervical Pathology (ASCCP) shall be utilized for reporting all Pap smear results.
- Women whose Pap smear specimen is inadequate or unsatisfactory shall receive a repeat Pap smear.
- Individuals with Bethesda Pap smear diagnoses categorized as requiring work up, all abnormal diagnoses with the exception of ASC-US and LSIL, shall be referred for a diagnostic work-up to include colposcopy or colposcopy directed biopsy endocervical curettage within 10 working days as receipt of abnormal test results. Work up for ASC-US and LSIL is per physician discretion.

Definition of Benign and Abnormal Pap-Smear Results

In May 2002, the CDS Expert Cervical Workgroup adopted the use of Bethesda (2001) diagnoses for cervical cancer screening as published in JAMA on April 24, 2002.

Benign

Negative for Intraepithelial Lesion or Malignancy

- Trichomonas Vaginalis
- Fungal organisms morphologically consistent with Candida species.
- Shift in flora suggestive of bacterial vaginosis
- Bacteria morphologically consistent with Actinomyces species.
- Cellular changes consistent with herpes simplex virus.
- Reactive cellular changes associated with:
 - Inflammation
 - Radiation (changes)
 - Intrauterine device (IUD)
 - Atrophy
 - Other

Abnormal

Epithelial Cell Abnormalities:

Squamous Cell

- Atypical squamous cells of undetermined significance (ASC-US)
- Atypical squamous cells of undetermined significance, cannot exclude HSIL (ASC-H)
- Low-grade squamous intraepithelial lesion (LSIL) encompassing: human papillomavirus (HPV)/mild dysplasia/cervical intraepithelial neoplasia (CIN I)
- High-grade squamous intraepithelial lesion (HSIL) encompassing: moderate and severe dysplasia, carcinoma in situ; cervical intraepithelial neoplasia (CIN II/CIN III)
- Squamous cell carcinoma (SCC)

Glandular Cell

- Atypical glandular cells (AGC) (specify endocervical, endometrial or not otherwise specified (NOS))
- Atypical glandular cells, favor neoplasia (specify endocervical or not otherwise specified (NOS))
- Endocervical adenocarcinoma in situ (AIS)
- Adenocarcinoma

Other (List above not comprehensive)

- Specify

5 SECTION FIVE: RESOURCES

5.1 *Regional Office Contractors*

A network of Regional Office Clinical Coordinators and Health Educators, funded by Cancer Detection Section (CDS) work with local physicians and other health care professionals, and community leaders to meet the needs of low-income underserved women. Among the network's activities are:

- Outreach & Support for Women – Regional Office Clinical Coordinators and local health care professionals work together to develop coordinated resources for women's breast and cervical care in local communities.
- Conducting tailored education, addressing the importance of routine screening and rescreening targeting priority populations which promote the early diagnosis and treatment of cancer.
- Advocating for low-income underserved women.

Regional Office Contractors work to make breast and cervical cancer a statewide public health priority and to develop collaborative relationships to deliver care. Their efforts in support of health professionals include:

- Continuing education and skills-based training.
- Recruitment of health care providers.
- Development of local networks of medical care
- Quality improvement of clinical services
- Technical assistance for timely diagnostic, treatment and tracking services

Information on Regional Office Contractors can be found at www.dhs.ca.gov/cancerdetection/

5.2 Professional and Public Education

The professional education objectives for *CDP:EWC* providers are to:

- Enhance providers' clinical practice and communication skills to assure a high quality, comprehensive approach to breast and cervical cancer screening and diagnosis.
- Provide training opportunities for Primary Care Providers (PCPs) to update knowledge and skills related to breast and cervical cancer screening and diagnosis.
- Offer providers information and strategies to help minimize barriers to breast and cervical screening, diagnosis and rescreening.

CDS has developed a professional education curriculum with three separate content modules that target primary care clinicians and their office staff. The modules are:

- Clinical Breast Examination: Proficiency and Risk Management
- Health Providers and Women: Partners in Communication
- Breast Cancer Review

Professional education resources may be obtained by contacting the Regional Office Clinical Coordinator.

5.3 Quality Assurance Project (QAP)

QAP is a collaborative effort between the San Diego State University, Graduate School of Public Health and CDS. The goal of the QAP is to improve breast and cervical cancer screening for California women. The QAP website is designed to serve as a resource for primary care clinicians. It provides program information related to the quality assurance project, the Breast Diagnostic Algorithms, Breast Cancer Review, and other educational materials. The web address is <http://qap.sdsu.edu>

5.4 Northern California Cancer Center (NCCC) 800 Number

The NCCC 800 number serves as a resource for women eligible for the CDS Program. Providers complete a survey for NCCC which specifies services available to women. When a woman calls requesting a referral to a program provider, NCCC provides women with names and addresses of PCPs in their area. Provider information is the same as in the Medi-Cal database of providers. It is important for providers to make certain that they report all provider changes

to Medi-Cal per Medi-Cal protocol. The NCCC assists providers by educating women on program eligibility and providing names of local participating PCPs.

Women who need services can call the Consumer Hot-line at (800) 511-2300. This service is available Monday through Friday, from 9 a.m. to 7 p.m. Operators are available in English, Spanish, Cantonese, Mandarin, Vietnamese, and Korean.

5.5 *Electronic Data Systems (EDS) Field Representatives*

EDS processes claims for services rendered to women in the *CDP:EWC*. Within EDS is The Telephone Service Center (TSC). The TSC assists providers with billing questions, claim submissions, and other inquiries related to billing. Field representatives are available for on-site training and workshops at no cost to the provider. To contact the TSC call (800) 541-5555.

5.6 *Point of Service/Internet Help Desk*

The Point of Service/Internet Help desk assists providers with access to data forms and responds to other Internet questions. The Help Desk/TSC can be reached at (800) 541-5555.

Regional Office Contractors

Region	Name	Counties
1	Partners for Cancer Prevention <i>(858) 554-5564</i>	San Diego, Imperial
2	Orange County Cancer Detection Partnership <i>(714) 834-7584</i>	Orange
3	Desert Sierra Partnership <i>(951) 697-6565 X 229</i>	Riverside, San Bernardino, Inyo
4	Partnered for Progress <i>(323) 549-0800</i>	Los Angeles
5	Tri-Counties Regional Partnership <i>(805) 681-4956</i>	Ventura, Santa Barbara, San Luis Obispo
6	Women's Health Partnership <i>(559) 244-4573</i>	Fresno, Kern, Kings, Madera, Mariposa, Merced, Stanislaus, Tulare, Tuolumne
7	SUCCESS Program <i>(831) 759-6598</i>	Monterey, San Benito, Santa Clara, Santa Cruz
8	Bay Area Breast and Cervical Health Collaborative <i>(510) 535-7386</i>	Alameda, Contra Costa, Marin, San Francisco, Dan Mateo, Solano
9	Gold Country Region <i>(916) 556-3344</i>	Alpine, Amador, Calaveras, El Dorado, Mono, Nevada, Placer, Sacramento, San Joaquin, Sierra, Sutter, Yolo, Yuba
10	Northern California Breast and Cervical Cancer Partnership <i>(530) 345-2483</i>	Butte, Colusa, Del Norte, Glenn, Humboldt, Lake, Lassen, Mendocino, Modoc, Napa, Plumas, Shasta, Siskiyou, Sonoma, Tehama, Trinity

6 SECTION SIX: BILLING

Cancer Detection Programs: Every Woman Counts (CDP:EWC) uses the Medi-Cal process for claims submission. Services can be billed electronically or by hard copy. However, Primary Care Providers (PCPs) must have Internet access to enroll women and obtain the recipient ID number required on each claim.

PCPs are responsible for managing patient services, which are screening, follow-up, and rescreening, as well as supplying clinical information on the *Online Breast/Cervical Cancer and Follow-up Forms*. The PCP will be reimbursed a case management fee after meeting all data requirements. Payment of case management can be claimed only once per patient per year. Data may be required after payment has been received. PCPs are required to submit all patient data regardless of ability to receive payment for case management.

Detailed Program claims reimbursement information is available in the CDP:EWC section of the Medi-Cal Manual

7 SECTION SEVEN: REFERRALS TO TREATMENT

The Breast and Cervical Cancer Treatment Program (BCCTP) offers treatment through the Medi-Cal Program for women and men with breast cancer, and women with cervical cancer who meet program entry eligibility criteria. Patients can only gain access to BCCTP through two types of providers: *Cancer Detection Programs: Every Woman Counts (CDP:EWC)* Primary Care Providers (PCPs) and Family Planning, Access, Care and Treatment (FPACT) providers.

Diagnoses Obtained Through CDP:EWC

Women already in *CDP:EWC* who are diagnosed with either breast cancer and/or cervical cancer (including CIN II and CIN III) can be referred into BCCTP. Providers are required to submit complete diagnostic and treatment data as specified in the Step-By-Step User Guide www.MediCal.ca.gov under Specialty Programs, Cancer Detection. Providers are to follow BCCTP enrollment procedures. For more BCCTP information, contact the Eligibility Specialist at the toll-free number (800) 824-0088. References to the BCCTP can be found in the Medi-Cal Manual and at <http://www.medi-cal.ca.gov>.

Diagnoses Obtained Outside CDP:EWC

Only patients eligible for *CDP:EWC* services can enter BCCTP through *CDP:EWC*. Therefore, men are not eligible to enter BCCTP through *CDP:EWC*. Women age twenty-five and above who are diagnosed with cervical cancer outside *CDP:EWC* may be enrolled into BCCTP by *CDP:EWC* providers. Women age forty and above who are diagnosed with breast cancer outside *CDP:EWC* may be enrolled into BCCTP by *CDP:EWC* providers. In these cases, the *CDP:EWC* provider must confirm that the woman does have documentation of either breast cancer and/or cervical cancer (including CIN II and CIN III). The provider must keep patient-signed documentation of the Recipient Eligibility form on file and be able to produce the documentation when asked. The woman is not to be enrolled into *CDP:EWC* and must not be issued a Recipient ID if screening services are not provided by *CDP:EWC*. Providers are to follow BCCTP enrollment procedures. For more BCCTP information, contact the Eligibility Specialist at the toll-free number (800) 824-0088. References to the BCCTP can be found in the Medi-Cal Manual and at <http://www.medi-cal.ca.gov>.

If the purpose of a patient's contact with the PCP is for referral into BCCTP, no office visit can be billed to *CDP:EWC*. The only office visits available to providers for this purpose are through BCCTP. For information about billing an office visit for the verification of a cancer diagnosis, providers are to refer to BCCTP resources listed above.

Billing *CDP:EWC* and Data Requirements

If a provider determines more testing is needed for a woman diagnosed outside *CDP:EWC* before confirming a cancer diagnosis, the provider may perform testing under *CDP:EWC*. The provider must understand that once billing occurs in *CDP:EWC*, the same data requirements apply as if the patient was screened within the *CDP:EWC* program. This means complete screening cycle data must be submitted on the online screening forms.